K083519

510(k) Summary of Safety and Effectiveness

APR 10 2009

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5352
CONTACT PERSON:	Frank Gianelli Senior Associate, Regulatory Affairs
DATE PREPARED:	November 24, 2008
TRADE/PROPRIETARY NAME:	Autosuture™ ENDO GIA™ Staplers
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staple
CLASSIFICATION NAME:	Staple, Implantable
PREDICATE DEVICE(S):	Autosuture™ ENDO GIA™ Stapler (K061095)

DEVICE DESCRIPTION:

The Autosuture™ ENDO GIA™ Staplers place two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows. The size of the staples is determined by the selection of the appropriate Single Use Loading Unit (SULU). The staplers will accommodate any of the single use loading units that are available in 30 mm, 45 mm and 60 mm lengths.

This 510(k) reports a new version of our currently marketed Autosuture™ ENDO GIA™ Staplers (K061095). This new version is considered a modification of the currently marketed Autosuture™ ENDO GIA™ Staplers. The modifications are as follows:

- Ergonomic and performance enhancements to the ENDO GIA™ Stapler Instrument.
- Addition of ENDO GIA™ Single Use Loading Units (SULUs) with Tri-Staple™ technology. Tri-Staple™ technology means that each of the two triple-staggered rows has a stepped configuration whereby the staples in the outer row are a taller height then the staples in the middle row which in turn are a taller height than the staples in the inner row. The ENDO GIA™ SULUs with Tri-Staple™ technology are available in articulating 30 mm, 45 mm and 60 mm length cartridges.
- Addition of ENDO GIA™ Single Use Loading Units (SULUs) which have a curved-tip anvil configuration. The curved-tip can be used to dissect and manipulate tissue when locating target tissue for subsequent firing and placement of staples.

INTENDED USE:	The Autosuture™ ENDO GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures. The Autosuture™ ENDO GIA™ Staplers when used with the ENDO GIA™ Curved-Tip Single Use Loading Units (SULUs) can be used to blunt dissect or separate target tissue from other certain tissue.
TECHNOLOGICAL CHARACTERISTICS:	Autosuture™ ENDO GIA™ Staplers are substantially equivalent to the predicate devices with regard to the stapling technologies. The addition of ENDO GIA™ Single Use Loading Units (SULUs) with Tri-Staple™ technology provide additional selection for the surgeon depending upon the tissue thickness to be transected or resected. The new ENDO GIA™ Curved-Tip Single Use Loading Unit (SULU) can be used to blunt dissect or separate target tissue from other certain tissue.
MATERIALS:	All components of the Autosuture™ ENDO GIA™ Staplers are comprised of materials that are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Bench and animal model performance evaluations were completed to verify that the Autosuture™ ENDO GIA™ Staplers with the new ENDO GIA™ Single Use Loading Units are safe and effective and perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Covidien
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

APR 10 2009

Re: K083519
Trade/Device Name: Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 3, 2009
Received: April 6, 2009

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K083519

Device Name: **Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units**

Indications For Use:

The Autosuture™ ENDO GIA™ Staplers with ENDO GIA™ Single Use Loading Units (SULUs) have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

The Autosuture™ ENDO GIA™ Staplers when used with the ENDO GIA™ Curved-Tip Single Use Loading Unit (SULUs) can be used to blunt dissect or separate target tissue from other certain tissue.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Hara for mkn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083519